

Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

14PY-129354

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed
name _____

Application Number

10/821,200

Filed

April 9, 2004

First Named Inventor

Gerald P. Schatten et al.

Art Unit

1632

Examiner

Thaian N. Ton

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record. 33,754
Registration number _____

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____



Signature

Don J. Pelto

Typed or printed name

202-218-0000

Telephone number

August 16, 2007

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 3 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	10/821,200	Confirmation No. 8230
Applicant	Gerald P. Schatten <i>et al.</i>	
Filed	April 9, 2004	
TC/Art Unit	1632	
Examiner	Thaian N. Ton	
Docket No.	14PY-129354	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314
MAIL STOP AF

Applicants respectfully request review of the final rejection in the above-identified application. No amendments are being filed with this request.

This Pre-Appeal Brief Request for Review is being filed concurrently with a Notice of Appeal and is submitted for the reasons stated on the attached sheets.

REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks. Claims 22, 23, 28-49 and 67-84 have been withdrawn from consideration. Claims 1-16, 21 and 85 are pending in the application.

Introduction

The Examiner's Advisory Action dated July 24, 2007, has maintained three rejections of the pending claims: (1) a provisional rejection for obviousness-type double patenting over co-pending application serial number 11/003,006 in view of Campbell (Cloning & Stem Cells, 3(4):201-208); (2) a rejection under 35 U.S.C. § 112, ¶2, for indefiniteness; and (3) a rejection under 35 U.S.C. § 112, ¶1, for lack of enablement. Applicants have agreed to address the provisional double patenting rejection once the claims are otherwise in condition for allowance. (July 16, 2007 Response at 7-8). Applicants also proposed amendments, as suggested by the Examiner in the Office Action of May 16, 2007 at page 13, to overcome the indefiniteness rejection. (July 16, 2007 response at 13-14). Should Applicants' proposed Amendments be entered, the Examiner's indefiniteness rejection would be mooted. The sole true dispute between the Examiner and Applicants is over the Examiner's rejection of the claims for lack of enablement.

The Examiner's Enablement Rejection

In the Office Action of August 15, 2006, the Examiner rejected the then pending claims for lack of enablement. (August 15, 2006, Office Action at 5-13). The crux of the Examiner's rejection was that the art showed great uncertainty in the production of a live cloned animal and that therefore the specification did not provide sufficient guidance so as to enable the claims. (August 15, 2006, Office Action at 7-13). In response, Applicants deleted the following language in the independent claim: "transferring said embryo to the oviducts of a female; and producing a cloned animal." (February 12, 2007, Response at 2). As amended, the claims now recited production of a "viable primate embryo" only and hence did not extend into the areas that were the basis for the Examiner's rejection. (*Id.* at 2). In addition, Applicants added new claim 85 which recited specific donor cells. (*Id.* at 6).

The Examiner's May 16, 2007 Final Office Action "maintained" the enablement

rejection “for reasons of record, advanced in the prior Office Action, mailed 8/15/06.” (May 16, 2007 Office Action at 5). Despite Applicants’ explicit amendment of the claims to remove the recitation of “producing a cloned animal,” inexplicably the Examiner ignored the amendments to the claims and maintained the enablement rejection based on the very language now absent.

(*See id.* at 7-8). The Examiner again maintained the rejection in the Advisory Action mailed on July 24, 2007.

The Examiner has Clearly Erred in Reading Deleted Language Back into the Claims

The Examiner asserts that the claims require production of a cloned animal. That language, however, is absent from the claims, which plainly recite production of a “viable primate embryo.” As Applicants argued in their July 16 Response, “viable primate embryo” has a clear meaning based upon the claim language and the specification. (July 16, 2007 Response at 9-10). Instead of interpreting the claims as they are drafted, the Examiner improperly interprets the claims in line with Examiner’s view of what the invention must be. (*See* July 24, 2007, Advisory Action at 2; May 16, 2007, Office Action at 7-8).

The Examiner’s interpretation is demonstrably incorrect. The Examiner’s interpretation improperly relies heavily upon Applicants’ restriction of the invention on May 31, 2006 in response to the Examiner’s May 3, 2006 Restriction Requirement. (*See* July 24, 2007 Advisory Action at 2; May 16, 2007 Office Action at 7-8). That Applicants elected the methods of “producing a cloned animal” over methods of “culturing . . . blastomeres to produce stem cells” does not mean that every claim Applicants subsequently submitted must be interpreted to result in “producing a cloned animal.” Notably, Applicants are not now claiming the non-elected subject matter because Applicants elected invention encompassed producing a “viable embryo.” Applicants’ presently claimed invention now does not require that the “viable embryo” be used to produced a cloned animal.¹ *Cf. Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) (“[T]he words of the claim are generally given their ordinary and customary meaning.”); *SRI Int’l v. Matsushita Elec. Corp.*, 775 F.2d

¹ Moreover, if Examiner believed Applicants amendments were improper, Examiner could have deemed Applicants’ February 12, 2007 Response to be unresponsive under MPEP § 821.03. It is not proper, however, for Examiner to simply interpret the amended claims to require a result that is no longer claimed.

1107, 1121, (Fed. Cir. 1985) (en banc). (“It is the claims that measure the invention.”). Following the Examiner’s position would illogically preclude any Applicants for patent from amending their claims at all in response to such rejections. *Cf. Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc.*, 98 F.3d 1563, 1568 (Fed. Cir. 1996) (discussing applicability of 35 U.S.C. § 121 as a shield to obviousness-type double patenting and noting “[a] restriction requirement does not prohibit subsequent amendments to the claims”).

As Applicants argued in great detail in their Responses, once the appropriate scope is given to the claims, the specification is enabling. (*E.g.*, February 12, 2007 Response at 10, 12-14; July 16, 2007 Response at 10-13). As such, Applicants request that the Panel reconsider and withdraw the rejection of the claims under 35 U.S.C. § 112, ¶1, for lack of enablement or re-open prosecution on the merits.

The Examiner has Clearly Erred in Failing to Separately Examine the Patentability of Claim 85

As Applicants argued in their July 16, 2007 response, the Examiner fails to consider the invention defined in claim 85. (July 16, 2007 Response at 13). In the Advisory Action, the Examiner again dismisses claim 85 with little analysis. (July 24, 2007 Advisory Action at 2). Applicants respectfully request that the Panel also review the effect of the specific limitations contained in claim 85 on the enablement analysis and Applicants request that the Panel reconsider and withdraw the rejection of the claims under 35 U.S.C. § 112, ¶1, for lack of enablement or re-open prosecution on the merits.

Conclusion

In light of the foregoing, Applicants respectfully request that the Panel re-open prosecution on the merits or withdraw the rejections of record and allow the claims as presently drafted.

If the Panel has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited. If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully Submitted,



Don J. Peltó
Reg. No. 33,754

August 16, 2007

Sheppard Mullin Richter & Hampton, LLP
1300 I Street NW, 11th Floor East
Washington, DC 20005
Telephone: (202) 218-0000
Facsimile: (202) 218-0020